

Decision Memo for Prothrombin Time and Partial Thromboplastin Time (Revision of ICD-9-CM Codes for Pre-operative Examinations) (CAG-00184N)

Decision Summary

This memorandum serves the purpose of addressing a request for adding codes for pre-operative examinations to the prothrombin time (PT) national coverage determination (NCD) and partial thromboplastin time (PTT) NCD. CMS intends to alter the list of covered diagnoses for partial thromboplastin time and prothrombin time tests by deleting the present line that reads V72.84 (Pre-operative examination, unspecified). We also intend to delete code V72.81 (Pre-operative cardiovascular examination) and V72.83 (Other specified pre-operative examination) from the list of covered codes for PTT.

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Decision Memo

To: Administrative File: CAG-00184N Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) (Revision of ICD-9-CM Codes for Pre-operative Examinations)

From:

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Re: Decision Memorandum for PT and PTT Testing for Pre-operative Examinations

Date: September 29, 2003

Decision

This memorandum serves the purpose of addressing a request for adding codes for pre-operative examinations to the prothrombin time (PT) national coverage determination (NCD) and partial thromboplastin time (PTT) NCD. CMS intends to alter the list of covered diagnoses for partial thromboplastin time and prothrombin time tests by deleting the present line that reads V72.84 (Pre-operative examination, unspecified). We also intend to delete code V72.81 (Pre-operative cardiovascular examination) and V72.83 (Other specified pre-operative examination) from the list of covered codes for PTT.

Background

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, the committee utilized evidence-based processes to develop 23 NCDs, which we promulgated through notice and comment. Two of these NCDs were for PT and PTT testing. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the PT and PTT testing NCDs, CMS determined that coverage of specific PT and PTT tests was reasonable and necessary for certain medical indications. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM codes covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM codes denied" and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM codes that do not support medical necessity" and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in these NCDs that any ICD-9-CM code not listed in either of the other ICD-9-CM sections would be categorized into group three.

The PT and PTT testing NCDs include inconsistent information with respect to coverage of pre-operative examinations. The PT NCD includes in the list of covered ICD-9-CM diagnosis codes code V72.84, pre-operative examination, unspecified. The PTT NCD includes in the covered list of ICD-9-CM diagnostic codes code V72.81 (Pre-operative cardiovascular examination,) code V72.83 (Other specified pre-operative examination,) and code V72.84 (Pre-operative examination, unspecified).

Procedural Background and Scope of Reconsideration

On February 10, 2003 CMS received a letter from Affiliated Healthcare Systems to reconsider the NCD for PT testing to add ICD-9-CM codes V72.81 (Pre-operative cardiovascular examination), V72.82 (Pre-operative respiratory examination), and V72.83 (Other specified pre-operative examination) to the list of covered diagnoses. The basis for the request was that these additional codes were pre-operative codes similar in nature to ICD-9-CM codes listed as covered for each test. ICD-9-CM code V72.84 (Pre-operative examination, unspecified) was listed as a covered code in the NCD for the PT test and ICD-9-CM codes V72.81 (Pre-operative cardiovascular examination,) V72.83 (other specified pre-operative examination) and V72.84 were listed as covered codes in the NCD for the PTT test. The requestor sought consistent covered status in both NCDs for all pre-operative codes. Because the requestor sought consistent treatment of all pre-operative codes, we included in our reconsideration the entire series of pre-operative codes. We posted an announcement of such reconsideration on our coverage website on February 27, 2003. We invited public comment through March 27, 2003. We received four comments summarized as follows.

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- An individual wrote noting her agreement with adding codes in the V series. But the commenter offered no new scientific or medical evidence demonstrating that the test is reasonable and necessary for those codes.
- Another individual wrote stating that she was very much in favor of adding code V72.83 to the NCDs for PT and PTT. The commenter explained that code V72.84 would never be used appropriately for a PT test since the PT test is specified and the V72.84 code is used for unspecified tests. But the commenter offered no new scientific or medical evidence demonstrating that the test is reasonable and necessary for the code proposed.
- The College of American Pathology wrote in support of changing the PT and PTT coverage determinations to add specified V codes to the list of covered diagnoses. But the professional organization offered no new scientific or medical evidence demonstrating that the test is reasonable and necessary in those circumstances.

- The American College of Surgeons noted that PT and PTT tests are very useful in assessing the risk of bleeding or thrombosis pre-operatively. This comment referred to a sentence included in the indications section of both NCDs addressing risk of bleeding or thrombosis. The commenter stated that there was no logical reason to permit the clinical circumstance of an unspecified pre-operative examination to qualify for coverage of PT tests, yet not permit a specified pre-operative examination to qualify. The professional organization offered no new scientific or medical evidence demonstrating that the test is reasonable and necessary in the clinical situations identified by the V codes of interest.

In sum, none of the commenters provided a rationale other than the fact that the unspecified code was covered in both NCDs in support of inclusion of the other pre-operative examination codes. No scientific literature was submitted by the requester or any of the four commenters.

General Review Methodology

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we clearly stated our intent that the narrative of the NCDs should reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage.

We reiterated this position in the November 23, 2001 final rule (66 FR 58795) in responding to public comments requesting the addition of numerous codes to the NCDs. That is, we stated that:

It is critical that the narrative indications for the proposed policy and the ICD-9-CM codes that support medical necessity be consistent. Thus, in order for us to add codes to the list of ICD-9-CM code that support medical necessity, those codes must either be determined to be an appropriate translation of an existing indication, or we must add a new indication for the test in the policy narrative.

The narratives had been developed applying evidence-based policies and we indicated that further revisions to the coverage list would be considered through an evidence-based decision making process based on relevant scientific literature. The final rule also noted that commenters had requested that codes V72.81, V72.82, and V72.83 be added to the PT NCD at that time but that these codes were not added because CMS staff did not believe they flowed from the narrative indications.

Further, in Program Memorandum AB 02-110 we stated our intent as follows:

The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, requests for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD.

CMS Analysis

Because no new scientific or medical evidence was provided by either the requestor or commenters, consistent with the review methodology set forth in the final rule and summarized in the section above, the purpose of the reconsideration is to determine whether coverage of the codes in question is consistent with the narrative of the NCDs that was developed using evidence-based policies in the negotiated rulemaking process and published on November 23, 2001.

In the PT and PTT NCD narratives, there is an expressed discussion of pre-operative assessment in the indications sections. Specifically, the PT NCD states the following:

“A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example:

- Evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy.
- Prior to the use of thrombolytic medication.”

The PTT NCD includes similar language but without inclusion of the second example. This language concerning pre-operative assessment in the PT and PTT narratives must be read consistently with the general language in the November 23, 2001 final rule concerning screening tests. Medicare has historically interpreted the provisions of the Medicare statute in section 1862(a)(7) and 1862(a)(1)(A) to prohibit coverage of screening services. The final rule from November 23, 2001 has numerous references to the lack of coverage for services that are furnished in the absence of signs or symptoms of illness or injury. For example, every policy includes a "Reasons for Denial" section that states:

“Tests for screening purposes that are performed in the absence of signs, symptoms, complaints or personal history of disease or injury are not covered except as explicitly authorized by statute.”

In addition, each NCD includes a coding guideline section indicating that: "Screening tests are performed when no specific sign, symptom, or diagnoses is present and the patient has not been exposed to a disease." Several other individual NCDs, such as the lipid NCD, include explicit statements regarding the exclusion of coverage for tests provided in the absence of signs or symptoms. In developing the NCDs for clinical laboratory services, we tried to be completely clear and consistent regarding Medicare's policy of excluding coverage of services furnished in the absence of signs, symptoms, and personal history of disease throughout the final rule and all instructions related to these NCDs.

With respect to V codes specifically, these constitute a supplementary classification of factors influencing health state and contact with health services. This classification is provided to deal with occasions when factors other than a disease or injury classifiable to categories 001-999 (the main part of ICD) are recorded as "diagnoses" or "problems." This can arise in three ways:

- a. When a person who is not currently sick encounters the health services for some specific purpose, such as to act as a donor of an organ or tissue, to receive prophylactic vaccinations, or to discuss a problem which is in itself not a disease or injury.
- b. When a person with a known disease or injury, whether it is current or resolving, encounters the health care system for a specific treatment of that disease or injury (e.g., dialysis for renal disease; chemotherapy for malignancy; cast change).
- c. When some circumstance or problem is present which influences the person's health status but is not in itself a current illness or injury. Such factors may be elicited during population surveys, when the person may or may not be currently sick, or be recorded as an additional factor to be borne in mind when the person is receiving care for some current illness or injury classifiable to categories 001-999. In this circumstance, the V code should be used only as a supplementary code and should not be the one selected for use in primary, single cause tabulations.

Thus, V codes are seldom appropriately considered as principal diagnoses and only infrequently would be the sole justification for Medicare coverage of any service. These codes do not indicate a specific history of bleeding, coagulopathy, or use of thrombolytic medication (which are the examples in the NCD narrative of when these tests would be covered).

We do not believe that the V72.81 and V72.82 codes are appropriate for PT and PTT tests for reasons other than the absence of signs and symptoms. Use of the V72.81 code indicates that the patient is having a cardiovascular exam prior to surgery to determine if the patient has a cardiovascular problem that would preclude the planned surgery or call for precautionary measures. The patient can be scheduled for any type of surgery, but the intent is to do a preoperative evaluation of any potential cardiovascular conditions. The same is true for code V72.82 in which case a respiratory exam is being conducted to find any potential respiratory conditions that might preclude or increase the risk of surgery. We do not believe that PT and PTT can appropriately be considered part of a cardiovascular or a respiratory exam.

Although the indications sections of the PT and PTT NCDs include a statement regarding assessment of risk of hemorrhage or thrombosis in patients who will undergo medical interventions known to be associated with increased risk of bleeding or thrombosis, the indications section does not provide for such testing for all individuals. Rather, the discussion of the negotiating committee and the examples included in the indication clarify that the test is reasonable and necessary when the patient has signs, symptoms or past personal history that indicates an increased surgical risk for this patient. The list of covered codes includes several conditions that potentially indicate bleeding problems. Further, patients who are taking anti-coagulant medication are on the covered list.

We do not believe that it is consistent with the narrative of the PT and PTT NCDs to provide routine pre-operative screening services for patients who demonstrate no signs, symptoms or past history of disease indicating that a PT or PTT test might be beneficial. Thus, we are not adding the V72.3 series of codes as requested. However, we would reconsider this determination if presented with new evidence.

We do agree with the concern of the requestor and commenters that it appears inconsistent to have code V72.84 (Unspecified pre-operative examination) included on the list of covered diagnoses for PT and PTT and to have codes V72.81 (Pre-operative cardiovascular examination) and V72.83 (Other specified pre-operative examination) in the list of covered diagnoses for PTT. The Committee developed these lists of codes with very little time for study and careful evaluation. The Committee was concerned with the possibility of errors in the NCDs and encouraged commenters to submit copies of medical literature supporting their recommendations for change (65 FR 13087).

We agree with the observation that use of code V72.84 (Unspecified pre-operative examination) is not technically appropriate for PT nor is it appropriate for PTT since both are specific tests to assess coagulation status. In addition, we do not believe that these or the other pre-operative codes in question appropriately flow from the narrative when taken in the context of the committee's discussion and the general prohibition on screening services discussed throughout the final rule. Thus, we intend to remove these codes from the lists in both NCDs, as we do not believe they appropriately flow from the indications contained in the NCDs.

We have noted that code V72.84 (Unspecified pre-operative examination) is contained in the urine culture and serum iron studies NCDs. Accordingly, we intend to initiate the process to reconsider these NCDs as well.

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